PCRM PHYSICIANS COMMITTEE FOR RESPONSIBLE MEDICINE
5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

May 25, 2006

Steve Johnson, Administrator
US Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Comments on the HPV test plan for the chemical Phosphorous acid, triphenyl ester, reaction products with dipropylene glycol

Dear Administrator Johnson:

The following are comments on the test plan for the chemical Phosphorous acid, triphenyl ester, reaction products with dipropylene glycol (CAS# 116265-68-o) for the HPV program, submitted by the Chemtura Corporation (Chemtura). These comments are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health and environmental protection organizations have a combined membership of more than ten million Americans.

Chemtura proposes several tests for this chemical, which is apparently also known by another name (3,6,8,11-tetraoxa-7-phosphatridecane-1,13-diol, 7-[2-(2-hydroxymethylethoxy)methylethoxy]tetramethyl-) and CAS # (36788-39-3).

According to early EPA comments, the "chemical" is actually a mixture of isomers, which is not mentioned in the test plan, and additional information is also missing from the robust summaries. As does EPA, we reserve our full comments for a complete test plan and robust summaries entry, and look forward to responding to Chemtura's full HPV submission, particularly since it is possible that components of the full chemical may have data already available.

At this time we would like to suggest, however, a strategy that could reduce Chemtura's ecotoxicity testing commitment. Recent European Union (EU) research suggests that an acute threshold (step-down) approach to ecotoxicity testing can eliminate fish testing for new chemicals (Jeram et al., 2005) and humane pharmaceuticals (Hutchinson et al., 2003) in many cases, based on the observation that fish are rarely more sensitive than algae and daphnia. Instead of conducting a fish median lethal concentration (LC50) test, the company would conduct an acute threshold test in which fish testing would be performed at one concentration only (the lowest EC50 concentration obtained with previous algae

and daphnia testing). We encourage Chemtura to incorporate this strategy into the revised test plan they have been asked to submit.

Finally, we are encouraged by Chemtura's proposal to complete the genotoxicity tests *in vitro,* as stated in the test plan text but we ask that the company amend Table 1 in the test plan, as currently it states that an *in vivo* genotoxicity test will be performed.

Thank you for your attention to this issue. We can be reached at 202-686-2210 ext. 335 or via email at *kstoick@pcrm.org* with any questions or concerns.

Sincerely,

Kristie Stoick, MPH
Research Analyst

Chad B. Sandusky, PhD
Director of Research

Hutchinson TH, *et* al. (2003) A strategy to reduce the numbers of fish used in acute ecotoxicity testing of pharmaceuticals. *Environ. Toxicol. Chem. 22: 303 I-3036.*

Jeram S, *et* al. (2005) A strategy to reduce the number of fish in acute ecotoxicity testing of new chemical substances notified in the European Union. *Regul. Toxicol. Pharmacol. 42:* 218-224.